

REMARKS

In the Final Office Action dated December 17, 2009, the Examiner requested a statement providing a complete address for Carl Reitz, rejected claims 4-17, 20-44, and 60-62 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,258,027 to Sternby ("*Sternby*"); and rejected claims 4-17, 20-44, and 60-62 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,011,384 to Goux ("*Goux*").

By this Amendment, Applicant has amended claim 24 to correct a minor informality and canceled claims 26 and 61 without prejudice or disclaimer. Accordingly, claims 4, 6-17, 20-25, 27-60, and 62 are currently pending. Claims 45-59 have been withdrawn by the Examiner.

Statement Regarding Address

In the Final Office Action the Examiner states that "Applicant (Carl Reitz) has not given a post office address in the application." (Final Office Action at 2.) The Examiner requested a "statement over applicant's signature providing a complete post office address." (Id.)

Applicant filed a Supplemental Application Data Sheet including the requested information on August 12, 2009. Referring to the requirements for an Oath and Declaration, the M.P.E.P. states that "[u]nless such information is supplied on an application data sheet in accordance with § 1.76, the oath or declaration must also identify . . . [t]he mailing address, and the residence if an inventor lives at a location which is different from where the inventor customarily receives mail." 37 CFR § 1.63 (emphasis added). The M.P.E.P. also states that "[s]upplemental application data sheets . . . [m]ay be subsequently supplied prior to payment of the issue fee either to

correct or update information in a previously submitted application data sheet, or an oath or declaration under § 1.63 or § 1.67." 37 CFR § 1.76 (emphasis added). Accordingly, because Applicant has filed an Application Data Sheet including the requested information, the Examiner's request has been satisfied.

Section 102 Rejections

Claims 4-17, 20-44, and 60-62 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Sternby* and rejected claims 4-17, 20-44, and 60-62 under 35 U.S.C. § 102(b) as being anticipated by *Goux*. The Examiner again contends that claims 1-36:

are drawn to and replete with functional and intended use language that does not structurally differentiate the controller. The controller of STERNBY is implicitly capable of manipulating the data from the sensor readings to determine the progress of the treatment . . . and directing treatment based on sensor readings and data calculations (see claims 26-49 of STERNBY).

(Office Action at 4.)

Applicant maintains that the claims' recitation of a "controller being configured to . . ." should be examined and given patentable weight. The U.S. Court of Appeals for the Federal Circuit is clear on this point. In *In re Lowry*, the Federal Circuit held that the programmed operations of a processor define structure. Citing, *Application of Bernhart*, *In re Lowry* stated that:

[t]here is one further rationale used by both the board and the examiner, namely, that the provision of new signals to be stored by the computer does not make it a new machine, i.e. it is structurally the same, no matter how new, useful and unobvious the result.... To this question we say that if a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program; its memory elements are differently arranged. The

fact that these physical changes are invisible to the eye should not tempt us to conclude that the machine has not been changed. (Emphasis added.)

In re Lowry, 32 F.3d 1579, 1583 (Fed. Cir. 1994) (citing *In re Bernhart*, 57 C.C.P.A. 737, 417 F.2d 1395, 1400, 163 USPQ 611, 615-16 (CCPA 1969)).

As stated in Applicant's previous reply, it is well established that an "[a]pplicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought." M.P.E.P. § 2173.01. Further, "[t]here is nothing inherently wrong with defining some part of an invention in functional terms." M.P.E.P. § 2173.05(g).

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.

M.P.E.P. § 2173.05(g).

Accordingly, the claims' recitation of a "controller being configured to . . ." should be examined and given patentable weight, and the Examiner's prior refusal to do so is wholly improper, based not only on the M.P.E.P. but on Federal Circuit law as well. Applicant respectfully requests reconsideration and reexamination of the claims.

Additionally, neither *Sternby* nor *Goux* anticipates independent claim 60 or independent claim 62. In order for a claim to be anticipated under Section 102, a prior art reference must disclose each and every element as set forth in the claim. See

M.P.E.P. 2131. *Sternby* and *Goux*, however, do not disclose each and every feature of independent claims 60 and 62.

Independent claim 60, inter alia, recites that the controller is configured to:

- determine at time intervals during treatment:
 - a parameter selected from the group consisting of an instantaneous clearance K_{Ti} measured at an elapsed treatment time T_i and a dialysance value D_{Ti} measured at an elapsed treatment time T_i ; and
 - an effective total dialysis dosage K^*T_{Ti} value which has been delivered at the elapsed treatment time T_i . . .
- compare said calculated dialysis dose K^*T_{Ti} to at least a total dialysis dosage value K^*T_p . . . [and]
- determine at least one timing selected from the group consisting of an estimated remaining treatment procedure time T_{tr} and an estimated total treatment time T_{tot} required for achieving said prescribed total dialysis dosage value K^*T_p

Sternby does not disclose "compar[ing] said calculated dialysis dose K^*T_{Ti} to at least a total dialysis dosage value K^*T_p to be achieved at the end of the treatment and to generate at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment," as recited in independent claim 60. Additionally, *Sternby* does not disclose determining "at least one timing selected from the group consisting of an estimated remaining treatment procedure time T_{tr} and an estimated total treatment time T_{tot} required for achieving said prescribed total dialysis dosage value K^*T_p ," as recited in independent claim 60. Rather, *Sternby* discloses "assessing the dialysis treatment on-line to determine the efficiency, the delivered dose, pre and post total urea masses in the body, the urea generation rate, the volume of distribution of urea in the body (for example by taking a blood sample for determining the urea concentration in the blood), and still further parameters

and variables." (Col 12, lines 32-37.) Thus, *Sternby* does not disclose each and every one of the claimed features.

Goux is directed to the calculation of clearance or of dialysance. Specifically, the method of *Goux* includes:

steps of flowing through the exchanger a treatment liquid having a concentration characteristic (C_d) and of varying the value of the characteristic (C_d) upstream of the exchanger for a time at the end of which the characteristic (C_d) is returned to a nominal value. A plurality of values adopted by the characteristic (C_d) downstream of the exchanger in response to the upstream variation is measured and stored in memory. The area (S_{out}) of a downstream perturbation region is determined, which is bounded by a baseline and a curve representing the variation of the measured values with respect to time. Then, the parameter ($D, K, Kt/v, C_{bin}$) indicative of the effectiveness of the treatment is calculated using the area (S_{in}) beneath the upstream curve and an area beneath an upstream curve.

(Abstract.) However, *Goux* does not disclose "compar[ing] said calculated dialysis dose $K \cdot T_{Ti}$ to at least a total dialysis dosage value $K \cdot T_p$ to be achieved at the end of the treatment and to generate at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment," as recited in independent claim 60. Additionally, *Goux* does not disclose determining "at least one timing selected from the group consisting of an estimated remaining treatment procedure time T_{tr} and an estimated total treatment time T_{tot} required for achieving said prescribed total dialysis dosage value KT_p ," as recited in independent claim 60. Thus, *Goux* does not disclose each and every one of the claimed features.

Applicant notes that dialysance (or clearance) and dialysis dose are distinct parameters representative of distinct concepts. Dialysance and clearance are expressions of the instant efficiency of the treatment. By contrast, dialysis dose is an expression of the cumulated blood depuration from undesired solutes over time.

As recited in independent claim 60, the controller is configured to compare the calculated dialysis dose $K \cdot T_{Ti}$ to the total dialysis dosage value $K \cdot T_p$ to be achieved at the end of the treatment. With this comparison, the controller can ensure that the desired total dialysis dose $K \cdot T_p$ will be delivered by the end of the treatment time.

Independent claim 62 is also patentable over the cited references. The concept behind the subject matter of independent claim 62 is that of a controller programmed to achieve two targets at the same time, namely a desired total weight loss (W_{Lp}) for the patient and a desired total dialysis dosage (K_{Tp}). Applicant notes that according to independent claim 62, a ratio R between W_{Lp} / K_{Tp} is created. At each time interval, the controller controls the fluid removal rate UF_{Ti} so that the ratio between fluid removal rate and instantaneous measured clearance (or dialysance), i.e. UF_{Ti} / K_{Ti} , is also kept equal to R .

Clearance and fluid removal rate are the derivatives over time respectively of W_{Lp} and K_{Tp} . As actual clearance and actual fluid removal rate are kept equal to R at each instant, the two targets W_{Lp} and K_{Tp} will both be achieved with no need to set or calculate a treatment time.

Sternby does not disclose "controlling the rate of fluid removal from the second compartment of the blood treatment, said controlling comprising keeping said rate of fluid removal UF_{Ti} at time T_i substantially equal to the product of said prescribed rate R

by the instantaneous clearance K_{Ti} or instantaneous dialysance value D_{Ti} measured at treatment time T_i ," as recited in independent claim 62. *Goux* also does not disclose "controlling the rate of fluid removal from the second compartment of the blood treatment, said controlling comprising keeping said rate of fluid removal UF_{Ti} at time T_i substantially equal to the product of said prescribed rate R by the instantaneous clearance K_{Ti} or instantaneous dialysance value D_{Ti} measured at treatment time T_i ," as recited in independent claim 62.

Accordingly, new independent claims 60 and 62 are allowable over *Sternby* and *Goux*. Claims 4, 6-17, 20-25, and 27-59 are allowable at least due to their dependence from independent claim 60 and due to their recitations of additional patentable subject matter.

Conclusion

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing the claims in condition for allowance. Applicant submits that the proposed amendments of the claims do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicant respectfully points out that the final action by the Examiner presented some new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of the Amendment

would allow the Applicant to reply to the final rejections and place the application in condition for allowance.

Finally, Applicant submits that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicant submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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